

HEALTH AND SENIOR SERVICES

DIVISION OF PUBLIC HEALTH SERVICES

DIVISION OF FAMILY HEALTH SERVICES

Screening of Children for Lead Poisoning

Proposed New Rules: N.J.A.C. 8:51A

Authorized By: Clifton R. Lacy, M.D., Commissioner, Department of Health
and Senior Services.

Authority: N.J.S.A. 26:2-137.2 et seq., particularly 26:2-137.7.

Calendar Reference: See Summary below for explanation of exception to calendar
requirement.

Proposal Number: PRN 2004-427.

Submit written comments by January 14, 2005 to:

Sylvia Dellas, Coordinator

Child and Adolescent Health Program

New Jersey Department of Health and Senior Services

P O Box 364

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The agency proposal follows:

Summary

N.J.S.A. 26:2-137.1 et seq. (P.L. 1995, c.328) (the “Law”), which became effective on March 5, 1996, was intended to help reduce and eventually eliminate childhood lead poisoning through lead screening of children under the age of six. The Law requires physicians, registered professional nurses, as appropriate, and licensed health care facilities that serve children, to perform lead screening on each child under six years of age to whom they provide health care services. N.J.S.A. 26:2-137.4. Health care providers that cannot perform this screening are required to refer the child to another health care provider that is able to perform lead screening. Id. Health care providers are not required to perform the screening on a child whose parent or guardian objects. Id.

The Law requires that blood lead tests to screen children for lead poisoning be performed by laboratories licensed by the Department, that laboratories report all blood lead test results to the Department, and that the Department maintain a database of lead screening results and report annually to the Governor and the Legislature. N.J.S.A. 26:2-137.5 and 137.6.

The Law directs the Department to promulgate regulations providing for specific implementation of the lead screening requirements, including the age of the child when initial screening shall be conducted, the time intervals between screening, when follow-up testing is required, and the methods to be used to conduct the lead screening. N.J.S.A. 26:2-137.4e and 137.7.

To implement the Law, the Department promulgated rules that became effective December 1, 1997 at N.J.A.C. 8:51A. 29 N.J.R. 990(a) (April 7, 1997); 29 N.J.R.

5081(a) (December 1, 1997). The Department filed a notice of proposal to readopt the chapter without change prior to the December 1, 2002 expiration date, thereby extending the expiration date to May 30, 2003, by operation of N.J.A.C. 1:30-6.4(f). 34 N.J.R. 4285(b) (December 16, 2002). The Department received two comments on the proposal. The Department did not take timely action on the proposal. N.J.A.C. 8:51A expired May 30, 2003, and the notice of proposal to readopt the chapter expired December 16, 2003. The Department proposes to adopt expired N.J.A.C. 8:51A as new rules. The new rules are identical to the rules previously in force, except that the phrase “as amended and supplemented” follows references to statutory and regulatory provisions in order to ensure that this chapter references subsequent amendments to the cited provisions.

The rules set forth the screening schedules and other requirements necessary to implement the Law. A summary of expired rules proposed as new follows:

N.J.A.C. 8:51A-1 would contain general provisions applicable to the chapter, and describes the entities subject to its provisions and the chapter’s purpose. It also would contain definitions of the following terms used throughout the chapter: “anticipatory guidance,” “Commissioner,” “confirmed elevated blood lead,” “currently accepted medical guidelines,” “Department,” “elevated blood lead,” “environmental follow-up,” “health care facility,” “lead screening,” and “registered professional nurse, as appropriate.”

N.J.A.C. 8:51A-2 would contain the requirements for screening, including who would be required to screen, the screening schedule, and provisions for referral to another provider to perform the screening and for parental refusal.

N.J.A.C. 8:51A-3 would contain the requirements for specimen collection and laboratory testing.

N.J.A.C. 8:51A-4 would contain the requirements for reporting of screening test results and medical follow-up of elevated results.

As the Department has provided a 60-day comment period for this notice of proposal, this notice is exempted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

Lead is a heavy metal that has been widely used in industrial processes and consumer products. When absorbed into the human body, lead affects the blood, kidneys and nervous system. The effects of lead on the nervous system are particularly serious and can cause learning disabilities, hyperactivity, decreased hearing, mental retardation and death. Research has shown that children under six years of age, especially children between six months and three years of age, are particularly sensitive to the adverse effects of lead exposure. Children who have suffered from the adverse effects of lead exposure for an extended period may require special health and educational services in order to assist them to develop to their potential as productive members of society.

The primary method for lead to enter the body is the ingestion of lead containing substances. Some common lead containing substances that are ingested or inhaled by children from six months through six years of age include:

- lead-based paint;

- dust and soil in which children play;
- tap water;
- food stored in lead soldered cans or improperly glazed pottery; and
- some folk remedies containing lead.

Because these and other lead-containing substances are present throughout the environment in New Jersey, all children in the State are at risk. Some children, however, are at particularly high risk due to exposure to high dose sources of lead in their immediate environment. These potential high dose sources include leaded paint that is peeling, chipped, or otherwise in a deteriorated condition, lead-contaminated dust created during removal or disturbance of leaded paint in the process of home renovation, and lead-contaminated dust brought into the home by adults who work in an occupation that involves lead or materials containing lead, or who engage in a hobby where lead is used.

State laws have helped to reduce the risk of lead exposure to some of New Jersey's children, but have not eliminated the risk. In recognition of the danger that lead-based paint presented to children, such paint was banned for residential use in New Jersey in 1971 and nationwide in 1978. These bans have effectively reduced the risk of lead exposure for children who live in houses built after 1978, but any house built before 1978 may contain leaded paint. Further, the highest risk to children is found in houses built before 1950, when paints contained a very high percentage of lead. Thirty percent of housing in New Jersey (2000 U.S. Census) was built before 1950. Every county in the State has more than 10,000 housing units built before 1950.

The Department's statistics regarding lead poisoning show that many children in New Jersey are suffering from the effects of lead exposure. More than 5,000 children were identified with elevated blood lead (10 µg/dL or higher) in New Jersey in State Fiscal Year 2003, despite the fact that only about 40 percent of the children are being screened. There are children identified with elevated blood lead in every county.

Screening children under six years of age is an important step in the prevention and early detection of childhood lead poisoning. Because the severity of the effects of lead exposure depend on the length of time during which a child is exposed, the well-being of children who are exposed to lead is dependent on early detection of elevated blood lead levels, followed by prompt medical and environmental intervention. The screening required by the Law and implemented by the expired rules proposed as new is intended to identify children and elevated blood levels at the ages when prompt intervention can prevent serious adverse effects from lead poisoning. The expired rules proposed as new attempt to strike a balance between targeting screening to those children at highest risk, while insuring that all children receive a minimum level of age-appropriate screening in accordance with the legislative mandate that all children be screened.

Economic Impact

Currently, laboratory charges for blood lead testing range from \$8.00 to \$50.00. The Department estimates that the average cost is approximately \$12.00. Because blood lead screening should be performed as part of routine primary care visits to physicians, there should be no other costs incurred in obtaining the screening.

N.J.S.A. 17:48E-35.10 requires that health service corporation contracts providing hospital or medical expense benefits for groups with greater than 50 persons cover the cost of lead screening of children, without co-payment or deductible.

Therefore, where applicable, the cost of this screening will be borne by insurers.

Many health maintenance organizations (HMOs) and other managed care organizations (MCOs) cover lead screening as part of their package of preventive services. Medicaid requires and pays for annual lead screening of all enrolled children under six years old. Additionally, local health departments, through their well-child services, can perform lead screening on children who do not have access to care in the private sector. There are, however, parents without medical insurance, who receive insurance through small groups, or who work for employers who self-insure, who will not have a third-party to pay for lead screening. Such parents will have an option to avoid the cost of the screening because the Law gives parents the ability to decline to have their children screened for lead poisoning for any reason, including the cost of the test.

The costs of lead screening are more than offset by the economic benefits resulting from reducing blood lead levels in children and from preventing the serious medical and developmental consequences of lead poisoning.

Federal Standards Statement

The expired rules proposed as new do not impose any requirements that exceed those imposed by Federal law or regulations. There are no Federal laws or regulations that are directly equivalent to the expired rules proposed as new. The only Federal regulation governing lead screening of children is a requirement of the U.S. Department

of Health and Human Services that applies only to children enrolled in Medicaid and requires children covered by Medicaid be screened annually. As the expired rules proposed as new are less stringent than this requirement, the Federal rules will continue to govern lead screening for Medicaid children in New Jersey. The expired rules proposed as new closely follow, and do not exceed, the policy statement "Preventing Lead Poisoning in Young Children," 4th revision, October 1991, of the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention. This and other publications relating to childhood lead poisoning prevention and screening are available at

http://www.cdc.gov/nceh/lead/publications/pub_Reas.htm, specifically at

<http://www.cdc.gov/nceh/lead/publications/books/plpyc/contents.htm>, or upon request

from the Centers for Disease Control and Prevention's Childhood Lead Poisoning Prevention Program at the following address: Childhood Lead Poisoning Prevention Branch, Centers for Disease Control and Prevention, #4470 Buford Highway (Mail stop F-30), Atlanta, GA 30341, Telephone: (770) 488-3300.

Jobs Impact

The implementation of the expired rules proposed as new approximately quadrupled the number of blood screening tests performed by New Jersey licensed clinical testing laboratories. Most blood lead testing is automated, so the laboratories should have been able to accommodate this increase with existing staff. However, the expired rules proposed as new may have resulted and may continue to result in an

increase in number of laboratory jobs for related activities, such as sample preparation and data entry.

Blood lead screening tests are done as part of regularly scheduled visits to health care providers. All health care providers have existing staffing arrangements to obtain blood samples for testing because screening and diagnostic testing are routinely conducted in medical practice. Therefore, although the expired rules proposed as new would require an increase in the number of test samples required to be obtained from patients, the Department believes the existing infrastructure has absorbed and would continue to absorb this increase and does not believe that the expired rules proposed as new have resulted or would result in an increase in the staffing requirements of health care providers.

Agricultural Industry Impact

The expired rules proposed as new have not had, and would not have, an impact on the agriculture industry in New Jersey.

Regulatory Flexibility Analysis

The expired rules proposed as new impose requirements on health care providers, many of which may be small businesses as defined under the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. All health care providers have arrangements to obtain blood samples from patients for clinical testing, so the requirement to obtain blood samples for lead screening should impose no additional burden on them. The requirement that parents be notified in writing of elevated results may impose a small

additional paperwork burden on health care providers. All costs associated with lead screening will be covered by the fees charged for screening, to be paid either by the child's parent or guardian or by the insurance carrier covering the child. As the expired rules proposed as new implement the requirements imposed on all health care providers by N.J.S.A. 26:2-137.2 et seq., which provides for no business-size related requirements or exemptions, none are provided in the expired rules proposed as new.

Smart Growth Impact

The expired rules proposed as new have not had and are not expected to have any impact on the achievement of smart growth and the implementation of the State Development and Redevelopment Plan.

Full text of the proposed new rules follows

CHAPTER 51A

SCREENING OF CHILDREN FOR LEAD POISONING

SUBCHAPTER 1. GENERAL PROVISIONS

8:51A-1.1 Scope and applicability

The rules in this chapter apply to physicians, registered professional nurses, as appropriate, and licensed health care facilities that provide services to children under six years of age, and to licensed clinical laboratories that perform blood lead testing.

8:51A-1.2 Purpose

The purpose of this chapter is to protect children under six years of age from the toxic effects of lead exposure by requiring lead screening pursuant to N.J.S.A. 26:2-137.2 et seq. (P.L. 1995, c.328).

8:51A-1.3 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

“Anticipatory guidance” means the provision of information regarding the major causes of lead poisoning and the means of preventing lead exposure to parents or guardians of children under six years of age.

“Commissioner” means the Commissioner of the New Jersey Department of Health and Senior Services.

“Confirmed elevated blood lead” means a blood lead test result on a venous blood sample equal to or greater than 10 micrograms per deciliter ($\mu\text{g}/\text{dL}$) of whole blood.

“Currently accepted medical guidelines” means that version of guidelines for the medical treatment of children with lead poisoning most recent to the time of evaluation, treatment and follow-up, published by a public health agency other than the Department, or recognized medical professional organization or agency, including the United States Centers for Disease Control and Prevention, the New Jersey Physicians Lead Advisory Committee, and the American Academy of Pediatrics.

“Department” means the New Jersey Department of Health and Senior Services.

“Elevated blood lead” means a blood lead test result, from either a venous or capillary sample, equal to or greater than 10 micrograms per deciliter ($\mu\text{g}/\text{dL}$) of whole blood.

“Environmental follow-up” means actions taken by a local health department to identify and remediate lead hazards in the environment of a child with elevated blood lead in accordance with Chapter XIII of the New Jersey State Sanitary Code, N.J.A.C. 8:51, as amended and supplemented.

“Health care facility” means a facility licensed to perform health care services pursuant to N.J.S.A. 26:2H-1 et seq., as amended and supplemented.

“Lead screening” means the taking of a blood sample from a person by either fingerstick (capillary blood) or venipuncture (venous blood) and its analysis by a licensed clinical laboratory to determine the person’s blood lead level.

“Registered professional nurse, as appropriate,” means a registered nurse, licensed by the New Jersey Board of Nursing, who would be permitted to perform lead screening on his or her own authority as part of advanced practice activities authorized by the Board of Nursing.

SUBCHAPTER 2. SCREENING

8:51A-2.1 Risk assessment and anticipatory guidance

(a) Every physician, registered professional nurse, as appropriate, or health care facility that provides health care services to a child who is at least six months of age, but under six years of age, shall:

1. Inquire if the child has been appropriately assessed and screened for elevated blood lead levels in accordance with this chapter;

2. If a risk assessment has not been performed within the 12 months, prior to the provision of services, perform a risk assessment and place the written notes from such assessment in the child’s medical record. The risk assessment shall include, at a minimum, questions to determine:

- i. Whether the child resides in, or frequently visits, a house built before 1960 in which the paint is peeling, chipping, or otherwise deteriorated, or where renovation work has recently been performed that involved the removal or disturbance of paint; and

- ii. Whether the child resides with an adult who is engaged in an occupation or hobby where lead or material containing lead is used; and

3. Provide the parent or guardian of each child with anticipatory guidance on lead poisoning prevention.

8:51A-2.2 Lead screening schedule

(a) Every physician, registered professional nurse, as appropriate, or health care facility, unless exempt pursuant to N.J.A.C. 8:51A-2.3, shall perform lead screening on each patient who is between six months and six years of age according to the following schedule:

1. Lead screening shall be performed on each child:

i. Between nine and 18 months of age, preferably at, or as close as possible to, 12 months of age; and

ii. Between 18 and 26 months of age, preferably at, or as close as possible to, 24 months of age. The second test shall be performed no sooner than six months following the first test.

2. For children found to be at high risk for lead exposure, as determined by the risk assessment performed pursuant to N.J.A.C. 8:51A-2.1:

i. Each child between six and 24 months of age shall be screened, unless he or she has been screened within the previous six months; and

ii. Each child between six months and six years of age shall be screened when the risk assessment indicates exposure to a new high dose source of lead since the last time that he or she was screened.

Examples of a new high dose source include, but are not limited to, a recent renovation of the child's residence (if built before 1960 or if lead-

based paint is known to be present), deterioration of the paint in the child's residence, moving into a house built prior to 1960 that has peeling, chipping, or deteriorated paint, or an adult living in the household undertaking a new job or hobby that involves exposure to lead.

3. Each child older than 26 months of age but less than six years of age shall be screened if the child has never previously been screened for lead poisoning.

8:51A-2.3 Exemptions

(a) A physician, registered professional nurse, as appropriate, or health care facility shall be exempt from the requirements of N.J.A.C. 8:51A-2.2 under the following circumstances:

1. If the physician, registered professional nurse, as appropriate, or health care facility does not have the capability to inform the parents or guardians of the blood lead test result and to ensure follow-up treatment in accordance with N.J.A.C. 8:51A-4.1 and 4.2. Any physician, registered professional nurse, as appropriate, or health care facility that is exempt under this section shall make a referral for screening, in writing, to the child's primary health care provider. If the child has no primary health care provider, a referral shall be made, in writing, to another health care provider, or to the local health department which has jurisdiction over the municipality in which the child lives for lead screening in accordance with these rules;

2. If a parent or legal guardian of a child refuses, for any reason, to have a lead screening test performed on their child. Such refusal shall be documented in writing on a form or document signed by the parent or legal guardian, and kept with the medical record of the child; or

3. If a child is brought to a physician, registered professional nurse, as appropriate, or health care facility for treatment of an emergency and, in the judgment of the provider, performing lead screening would interfere with the prompt treatment of the emergency.

SUBCHAPTER 3. SPECIMEN COLLECTION AND LABORATORY TESTING

8:51A-3.1 Specimen collection

(a) Screening for lead poisoning shall be by blood lead test.

(b) Venous blood is the preferred specimen for blood lead analysis and should be used for lead measurement whenever practicable.

(c) A capillary blood specimen collected by fingerstick is acceptable for lead screening, if appropriate collection procedures are followed to minimize the risk of environmental lead contamination.

8:51A-3.2 Laboratory testing

(a) All blood lead samples collected for lead screening in accordance with this chapter shall be sent for testing to a clinical laboratory licensed by the Department in accordance with N.J.A.C. 8:44-2, as amended and supplemented.

(b) Laboratories shall report the results of blood lead testing to the Department in accordance with N.J.A.C. 8:44-2.11, as amended and supplemented.

SUBCHAPTER 4. FOLLOW-UP OF LEAD SCREENING RESULTS

8:51A-4.1. Reporting of lead screening results

(a) Each physician, registered professional nurse, as appropriate, or health care facility that screens a child for lead poisoning shall provide the parent or legal guardian with the results of the blood lead test and an explanation of the significance of the results.

(b) For each child who has a blood lead test, on a venous blood sample, greater than or equal to 15 micrograms per deciliter, the physician, registered professional nurse, as appropriate, or health care facility shall notify, in writing, the child's parent or guardian of the test results and provide the parent or guardian with an explanation in plain language of the significance of the results.

8:51A-4.2 Medical follow-up of lead screening results

(a) Each physician, registered professional nurse, as appropriate, or health care facility that screens a child for lead poisoning shall provide or make reasonable efforts to ensure the provision of risk reduction education and nutritional counseling for each child with a blood lead level equal to or greater than 10 micrograms per deciliter of (mg/dl) whole blood.

(b) The physician, registered professional nurse, as appropriate or health care facility shall obtain, or make reasonable efforts to obtain, a venous confirmatory blood

lead test whenever a capillary blood lead screening sample produces a result greater than or equal to 10 micrograms per deciliter ($\mu\text{g/dL}$).

(c) For each child who has a blood lead level of 10 micrograms per deciliter ($\mu\text{g/dL}$) or greater on a test performed with a venous blood sample, the physician, registered professional nurse, as appropriate, or health care facility shall provide, or make reasonable efforts to ensure, the provision of diagnostic evaluation, medical treatment, and follow-up blood lead testing in accordance with currently accepted medical guidelines.

(d) To the extent permitted by New Jersey law regarding patient confidentiality, the physician, registered professional nurse, as appropriate, or health care facility shall cooperate with local health departments by providing information needed to ensure case management and environmental follow-up as specified in Chapter XIII of the New Jersey State Sanitary Code, N.J.A.C. 8:51, as amended and supplemented.

(e) When a physician, registered professional nurse, as appropriate, or health care facility performs lead screening on a child and receives a result of 10 micrograms per deciliter ($\mu\text{g/dL}$) or greater on a test performed with a venous blood sample, the physician, registered professional nurse, as appropriate, or health care facility shall perform lead screening of all siblings or other members of the same household who are between six months and six years of age, if these children have not been screened previously, or at high risk for lead exposure, as determined by a risk assessment performed in accordance with N.J.A.C. 8:51A-2.2.